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10/805,290

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James Samsoondar

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EXAMINER

VO, HIEN XUAN

ART UNIT

PAPER NUMBER

2863

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/805,290

Applicant(s)

SAMSOONDAR

Examiner

Hien X. Vo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 29-80 is/are rejected.
- 7) ☒ Claim(s) 21 and 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/22/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-22 and 27-80 rejected under the judicially created doctrine of double patenting over claims 1-107 of U. S. Patent No. 6,771,516 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:

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1. A method for Calibration Algorithm Transfer comprising:
(i) obtaining a first set of absorbance measurements of a set of calibrators on a First Apparatus for at least one wavelength from a first wavelength calibration table;
(ii) establishing a second wavelength calibration table on a second apparatus, said first and said second wavelength calibration table may be the same or different, and obtaining a second set of absorbance measurements of a similar set of calibrators on said Second Apparatus, for at least one wavelength from said second wavelength

1. A method for Calibration Algorithm Transfer comprising:
(i) obtaining a first set of absorbance measurements of a set of calibrators on a First Apparatus that is in control at wavelengths from a first wavelength calibration table;
(ii) establishing a second wavelength calibration table on a second apparatus, said first and said second wavelength calibration table may be the same or different, and obtaining a second set of absorbance measurements of said set of calibrators on said Second Apparatus, at wavelengths from said second wavelength calibration

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<p>calibration table;</p> <p>(iii) determining a first interpolated absorbance for said first absorbance measurements for at least one wavelength of a Standard Set of Wavelengths, and determining a second interpolated absorbance for said second absorbance measurements for said at least one wavelength of said Standard Set of wavelengths,</p> <p>(iv) deriving a First Linear Regression Equation for at least one wavelength of said Standard Set of Wavelengths using said first and said second interpolated absorbance measurements; and</p> <p>(v) incorporating said First Linear Regression Equation and at least one Primary Calibration Algorithm onto said Second Apparatus.</p>	<p>table,</p> <p>(iii) determining a first interpolated absorbance for said first absorbance measurements for at least one wavelength of said Standard Set of Wavelengths, and determining a second interpolated absorbance for said second absorbance measurements for said at least one wavelength of said Standard Set of Wavelengths,</p> <p>(iv) deriving a First Linear Regression Equation for each of said at least one wavelength of said Standard Set of Wavelengths using said first and said second interpolated absorbance measurements,</p> <p>(v) incorporating said First Linear Regression Equation and at least one Primary Calibration Algorithm onto said Second Apparatus..</p>
<p>2. A method of determining concentration of an analyte in a sample in a second apparatus comprising:</p> <p>(a) performing a Calibration Algorithm Transfer according to the method of claim 1;</p> <p>(b) measuring an absorbance of said sample on said second apparatus, and determining a sample interpolated absorbance for at least one wavelength of said Standard Set of wavelengths;</p> <p>(c) adjusting said interpolated absorbance with said First Linear Regression Equation to obtain an Adjusted Interpolated Absorbance; and</p> <p>(d) calculating a concentration for said analyte by applying said at least one Primary Calibration Algorithm for said analyte to said Adjusted Interpolated Absorbance.</p> <p>3. The method according to claim 2, wherein in said step of obtaining (step (i)), and said step of measuring (step (b)), said <u>sample</u> and said set of calibrators, or <u>said similar set of calibrators</u> are placed within a like vessel having optical properties substantially similar to that used for the Primary Calibration.</p> <p>5. The method according to claim 2, wherein in said step of measuring (step (b)), said sample is any biological or non-biological fluid, and said analyte is any substance in said sample <u>for which an absorbance measurement can be obtained</u>.</p> <p>6. The method according to claim 2, wherein in said step of measuring (step(b)), said sample is a solid, and said analyte is any substance in said sample for which an absorbance measurement can be obtained.</p> <p>4. The method according to claim 3, wherein said vessel is selected from the group consisting of a pipette tip, a labeled test tube, an unlabeled test tube, blood bag tubing, a transparent sample container, and a translucent sample container.</p> <p>16. The method according to claim 1, wherein in said step of obtaining (Step (i)), <u>and in said step of establishing (step (ii))</u>, two or more calibrators are used.</p> <p>17. The method according to claim 16, wherein said set of calibrators, <u>or said set of similar calibrators</u>, used on both said First Apparatus and said Second Apparatus, are from the same batch.</p> <p>18. The method according to claim 16, wherein said set of calibrators, <u>or said set of similar</u> calibrators, comprise any material suitable for simulating absorbances and for producing said First Linear Regression Equation.</p> <p>19. The method according to claim 18, wherein said set of calibrators used on said First Apparatus are the same as said set of calibrators used on said Second Apparatus.</p> <p>14. The method according to claim 2, wherein in said step of</p>	<p>2. A method of determining concentration of an analyte in a sample in second apparatus comprising: .</p> <p>(a) performing a Calibration Algorithm Transfer according to the method of claim 1,</p> <p>(b) measuring an absorbance of said sample on said second apparatus, and determining a sample interpolated absorbance for at least one wavelength of said Standard Set of wavelengths,</p> <p>(c) adjusting said interpolated absorbance with said First Linear Regression Equation to obtain an Adjusted Interpolated Absorbance; and</p> <p>(d) calculating a concentration for said analyte by applying said at least one Primary Calibration Algorithm for said analyte to said Adjusted Interpolated Absorbance.</p> <p>3. The method according to claim 2, wherein in said step of obtaining (step (i)), and said step of measuring (step (b)), said set of calibrators and said sample are placed within a like vessel having optical properties substantially similar to that used for the Primary Calibration</p> <p>4. The method according to claim 2, wherein in said step of measuring (step (b)), said sample is any biological or non-biological fluid, and said analyte is any substance in said sample that can be measured.</p> <p>5. The method according to claim 2, wherein in said step of measuring (step(b)), said sample is a solid, and said analyte is any substance in said sample for which an absorbance measurement can be obtained.</p> <p>6. The method according to claim 3, wherein said vessel is selected from the group consisting of a pipette tip, a labeled test tube, an unlabeled test tube, blood bag tubing, a transparent sample container, and a translucent sample container.</p> <p>7. The method according to claim 1, wherein in said step of obtaining (Step (i)), two or more calibrators are used.</p> <p>8. The method according to claim 7, wherein said set of calibrators, used on both said First Apparatus and said Second Apparatus, are from the same batch.</p> <p>9. The method according to claim 8, wherein said set of calibrators comprise any material suitable for simulating absorbances and for producing at least one of said First Linear Regression Equation.</p> <p>10. The method according to claim 9, wherein said set of calibrators used on said First Apparatus are the same as said set of calibrators used on said Second Apparatus.</p> <p>11. The method according to claim 1, wherein in said step of <u>determining (step (iii))</u>, <u>said Standard Set of Wavelengths comprises</u></p>

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<p>measuring (step (b)), said Standard Set of Wavelengths comprises wavelengths from about 300 nm to about 2500 nm.</p> <p>15. The method according to claim 2, wherein, in said step of measuring (step (b)), said Standard Set of Wavelengths comprises wavelengths from about 500 nm to about 1100 nm.</p> <p>22. The method according to claim 1, wherein in said step of obtaining (step (i)), said first set of absorbance measurements, and in said step of establishing (step (ii)), said second set of absorbance measurements, or both said first and said second set of absorbance measurements, are determined one or more times at each wavelength of a wavelength calibration table, and either:</p> <ul style="list-style-type: none"> - an average of said first interpolated absorbance or said second interpolated absorbance value is mapped to said Standard Set of Wavelengths, or - an average of said first absorbance measurements or an average of said second absorbance measurements is interpolated and mapped to a standard set of wavelengths. <p>7. The method according to claim 2, wherein, in said step of measuring (step (b)), said Standard Set of Wavelengths, used by both said first Apparatus and said Second Apparatus, are the same.</p> <p>8. The method of claim 2, wherein in said step of measuring (step (b)), said standard set of wavelengths is derived from said first, said second, or both said first and said second wavelength calibration table.</p>	<p>determining (step (iii)), said Standard Set of Wavelengths comprises wavelengths from about 300nm to about 2500 nm.</p> <p>12. The method according to claim 1, wherein, in said step of determining (step (iii)), said Standard Set of Wavelengths comprises wavelengths from about 500 nm to about 1100nm.</p> <p>13. The method according to claim 1, wherein in said step of obtaining (step (i)), said first absorbance measurements, said second absorbance measurements, or both said first and said second absorbance measurements, are determined one or more times at each wavelength of a wavelength calibration table, and either,</p> <ul style="list-style-type: none"> - an average of said first interpolated absorbance or said second interpolated absorbance value is mapped to said Standard Set of Wavelengths, or - an average of said first absorbance measurements or an average of said second absorbance measurements is interpolated and mapped to a standard set of wavelengths. <p>14. The method according to claim 2, wherein, in said step of measuring (step (b)), said Standard Set of Wavelengths, used by both said first Apparatus and said Second Apparatus, are the same.</p> <p>15. The method of claim 2, wherein, in said step of determining (step (iii)), and wherein in said step of measuring (step (b)), said standard set of wavelengths is derived from said first or said second wavelength calibration table.</p>
<p>23. The method according to claim 1, wherein in said step of obtaining (step (i)), said first wavelength calibration table, in said step of establishing (step (ii)), said second wavelength calibration table, or both said first and said second wavelength calibration tables are obtained by:</p> <ul style="list-style-type: none"> (i) projecting a first electromagnetic radiation of known wavelength, onto a first pixel of a first linear diode array of said first apparatus, or a second linear diode array of said second apparatus; (ii) using a second electromagnetic radiation of known wavelength, said second electromagnetic radiation having a different wavelength than said first electromagnetic radiation, projecting said second electromagnetic radiation onto a second pixel of said first or said second linear diode array; (iii) identifying said first and second pixels within said first or said second linear diode array; (iv) calculating a pixeldispersion for said first or said second linear diode array; and (v) assigning a wavelength to each pixel within said first or said second linear diode array to produce said wavelength calibration table using said pixeldispersion and either said first electromagnetic radiation of known wavelength, and said first pixel, or said second electromagnetic radiation of known wavelength and said second pixel. <p>25. The method according to claim 1, wherein in said step of obtaining (step (i)), said first wavelength calibration table, in said step of establishing (step (ii)), said second wavelength calibration table, or both said first and second wavelength calibration tables are obtained by:</p> <ul style="list-style-type: none"> (a) projecting a known wavelength of electromagnetic radiation, onto a pixel in a linear diode array of said first apparatus, or said second apparatus; (b) identifying pixel number of said pixel; (c) assigning a wavelength to each pixel within said linear diode array to produce said first, second, or both said first and said second wavelength calibration table using a predetermined pixeldispersion, said known wavelength of electromagnetic radiation, and said pixel number. 	<p>16. The method according to claim 15, wherein said wavelength calibration table for said first apparatus or said second apparatus is obtained by:</p> <ul style="list-style-type: none"> (i) projecting a first electromagnetic radiation of known wavelength, onto a first pixel of a first linear diode array of said first apparatus, or a second linear diode array of said second apparatus, (ii) using a second electromagnetic radiation of known wavelength, said second electromagnetic radiation having a different wavelength than said first electromagnetic radiation, projecting said second electromagnetic radiation onto a second pixel of said first or said second linear diode array; (iii) identifying said first and second pixels within said first or said second linear diode array; (iv) calculating a pixeldispersion for said first or said second linear diode array; and (v) assigning a wavelength to each pixel within said first or said second linear diode array to produce said wavelength calibration table using said pixeldispersion and either said first electromagnetic radiation of known wavelength, and said first pixel, or said known wavelength and said second pixel. <p>17. The method according to claim 15, wherein said first wavelength calibration table for said first apparatus is obtained by:</p> <ul style="list-style-type: none"> (a) projecting a known wavelength of electromagnetic radiation, onto a pixel in a linear diode array of said first apparatus, (b) identifying pixel number of said pixel, (c) assigning a wavelength to each pixel within said linear diode array to produce said wavelength calibration table using a predetermined pixeldispersion, said known wavelength of electromagnetic radiation, and said pixel number.

26. The method according to claim 25, wherein said steps of projecting (step (a)), identifying (step (b)), and assigning (step (c)) are repeated on said second apparatus, and wherein said electromagnetic radiation of known wavelength is projected onto a pixel of a second linear diode array of said second apparatus having said pixel number, whereby said first apparatus and said second apparatus produce said first and second wavelength calibration tables, respectively, and said wavelength calibration table is used as a standard set of wavelengths.

28. The method according to claim 25, wherein said steps of projecting (step (a)), identifying (step (b)), and assigning (step (c)) are repeated on said second apparatus, and wherein said electromagnetic radiation of known wavelength is projected onto a pixel of a second linear diode array of said second apparatus, having a different pixel number.

29. The method according to claim 28, wherein said standard set of wavelengths is obtained by:

(A) establishing a set of wavelengths common to said wavelength calibration table of both said first and said second apparatus; and
(B) selecting a range of wavelengths of said set of wavelengths, said range of wavelengths having wavelengths belonging to said standard set of wavelengths.

80. The method of claim 79 wherein said range of wavelengths is about ± 10 nm.

81. The method of claim 79 wherein said range of wavelengths is about ± 5 nm.

82. The method of claim 79 wherein said range of wavelengths is about ± 2 nm.

9. The method according to claim 2, wherein in said step of adjusting (step (c)), said adjusted interpolated absorbance is obtained using the following equation:

Adjusted Interpolated Absorbance = (interpolated absorbance - y-intercept)/slope;

wherein, interpolated absorbance is as determined in said step of measuring (step (b)); and "y-intercept" and "slope" are obtained from said first linear regression equation, where said First Linear Regression Equation is derived from a plot of interpolated absorbance measurements, said first interpolated absorbance measurements on an X-axis, and said second interpolated absorbance measurements on a Y-axis, said First linear regression equation having a y-intercept and a slope.

18. The method according to claim 17, wherein said steps of projecting (step (a)), identifying (step (b)), and assigning (step (c)) are repeated on said second apparatus, and wherein said electromagnetic radiation of known wavelength is projected onto a pixel of a second linear diode array of said second apparatus having said pixel number, whereby said first apparatus and said second apparatus produce said first and second wavelength calibration tables, respectively, and said wavelength calibration table is used as a standard set of wavelengths.

19. The method according to claim 17, wherein said steps of projecting (step (a)), identifying (step (b)), and assigning (step (c)) are repeated on said second apparatus, and wherein said electromagnetic radiation of known wavelength is projected onto a pixel of a second linear diode array of said second apparatus, having a different pixel number.

20. The method according to claim 19, wherein standard set of wavelengths is obtained by:

(A) establishing a set of wavelengths common to said wavelength calibration table of both said first and said second apparatus, and
(B) selecting a range of wavelengths of said set of wavelengths, said range of wavelengths having wavelengths belonging to said standard set of wavelengths.

22. The method of claim 21 wherein said range of wavelengths is about ± 10 nm.

23. The method of claim 21 wherein said range of wavelengths is about ± 5 nm.

24. The method of claim 21 wherein said range of wavelengths is about ± 2 nm.

25. The method according to claim 2, wherein in said step of adjusting (step (c)), said adjusted interpolated absorbance is obtained using the following equation:

Adjusted Interpolated Absorbance = (interpolated absorbance - y-intercept)/slope;

wherein, interpolated absorbance is as determined in said step of measuring (step (b)); and "y-intercept" and "slope" are obtained from said first linear regression equation, where said First Linear Regression Equation is derived from a plot of interpolated absorbance measurements, said first interpolated absorbance measurements on an X-axis, and said second interpolated absorbance measurements on a Y-axis, said First linear regression equation having a y-intercept and a slope.

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<p>37. A method for Recalibrating an apparatus, said apparatus comprising at least one Primary Calibration Algorithm, said method comprising:</p> <ul style="list-style-type: none"> (i) obtaining absorbance measurements for at least one wavelength from a wavelength calibration table of a set of calibrators on said apparatus, said set of calibrators having assigned absorbance values for at least one wavelength of a standard set of wavelengths; (ii) determining interpolated absorbance values for said absorbance measurements for at least one wavelength of a Standard Set of Wavelengths; (iii) establishing a Second Linear Regression Equation in said apparatus for at least one wavelength of said standard set of wavelengths, using said interpolated absorbance values and said assigned absorbance values; and (iv) incorporating said Second Linear Regression Equation on said apparatus to produce a recalibrated apparatus. <p>38. A method of determining the concentration of an analyte in a sample in a Recalibrated apparatus comprising:</p> <ul style="list-style-type: none"> (a) recalibrating said apparatus according to the method of claim 37; (b) measuring an absorbance measurement of said sample for at least one wavelength from said wavelength calibration table; (c) deriving an interpolated absorbance for said absorbance measurement for at least one wavelength of said Standard Set of Wavelengths in said recalibrated apparatus; (d) adjusting said interpolated absorbance measurement with said Second Linear Regression Equation to obtain an Adjusted Interpolated Absorbance; and (e) calculating a concentration for said analyte by applying said Primary Calibration Algorithm for said analyte to said Adjusted Interpolated Absorbance. <p>39. The method according to claim 38, wherein in said step of obtaining (step (i)) said set of calibrators, and in said step of measuring (step (b)) said samples are placed within a like vessel having optical properties substantially similar to that used for Primary Calibration.</p> <p>41. The method according to claim 37, wherein in said step of measuring (step (b)), said sample is any biological or non-biological fluid, and said analyte is any substance in said sample for which an absorbance measurement can be obtained.</p> <p>42. The method according to claim 37, wherein in said step of measuring (step(b)), said sample is a solid, and said analyte is any substance in said sample for which an absorbance measurement can be obtained.</p> <p>40. The method according to claim 39, wherein said vessel is selected from the group consisting of a pipette tip, a labeled test tube, an unlabeled test tube, blood bag tubing, a transparent sample container, and a translucent sample container.</p> <p>52. The method according to claim 37 wherein in said step of obtaining (step (i)), two or more Calibrators are used.</p>	<p>26. A method for Recalibrating an apparatus <u>that is no longer in control</u>, said apparatus comprising a Primary Calibration Algorithm transferred according to the method to claim 1, said method comprising:</p> <ul style="list-style-type: none"> (i) obtaining absorbance measurements of a set of calibrators on said apparatus, said set of calibrators having assigned absorbance values, said apparatus comprising a Primary Calibration Algorithm, (ii) determining interpolated absorbance values for said absorbance measurements for at least one wavelength of a Standard Set of Wavelengths, (iii) establishing a Second Linear Regression Equation in said apparatus, using said interpolated absorbance values and said assigned absorbance values, and (iv) incorporating said Second Linear Regression Equation on said apparatus to produce a recalibrated apparatus. <p>27. A method of determining the concentration of an analyte in a sample in a Recalibrated apparatus comprising:</p> <ul style="list-style-type: none"> (a) recalibrating said apparatus according to the method of claim 26 (b) measuring an absorbance measurement of said sample; (c) deriving an interpolated absorbance for said absorbance measurement for at least one wavelength of said Standard Set of Wavelengths in said recalibrated apparatus; (d) adjusting said interpolated absorbance measurement with said Second Linear Regression Equation to obtain an Adjusted Interpolated Absorbance, and (e) calculating a concentration for said analyte by applying said Primary Calibration Algorithm for said analyte to said Adjusted Interpolated Absorbance. <p>29. The method according for claim 27, wherein in said step of obtaining (step (i)) said set of calibrators, and in said step of measuring (step (b)) said samples are placed within a like vessel having optical properties substantially similar to that used for Primary Calibration.</p> <p>30. The method according to claim 27, wherein in said step of measuring (step (b)), said sample is any biological or non-biological fluid, and said analyte is any substance in said sample that can be measured.</p> <p>31. The method according to claim 27, wherein in said step of measuring (step(b)), said sample is a solid, and said analyte is any substance in said sample that can be measured.</p> <p>32 The method according to claim 29, wherein said vessel is selectec from the group consisting of a pipette tip, a labeled test tube, an unlabeled test tube, blood bag tubing, a transparent sample container, and a translucent sample container.</p> <p>33. The method according to claim 26 wherein in said step of obtaining (step (i)), two or more Calibrators are used.</p>
<p>54. The method according to claim 52, wherein said set of calibrators comprise any material suitable for simulating absorbances and for producing at least one of said Second Linear Regression Equation.</p>	<p>35. The method according to claim 33, wherein said set of calibrators comprise any material suitable for simulating absorbances and for producing at least one of said Second Linear Regression Equation.</p>

17. The method according to claim 16, wherein said set of calibrators, or said set of similar calibrators, used on both said First Apparatus and said Second Apparatus, are from the same batch.

43. The method according to claim 38, wherein in said step of determining (step (ii)), and said step of deriving (step (c)), said Standard Set of Wavelengths comprise wavelengths from about 300 nm to about 2500 nm.

44. The method according to claim 38, wherein, in said step of determining (step ii), and said step of deriving (step (c)), said Standard Set of Wavelengths comprise wavelengths from about 500 nm to about 1100 nm.

45. The method according to claim 38, wherein in said step of obtaining (step (i)), said absorbance measurements are determined one or more times at each wavelength of a wavelength calibration table, and either an average of said first interpolated absorbance value is mapped to said Standard Set of Wavelengths, or an average of said first absorbance measurements is interpolated and mapped to a standard set of wavelengths.

46. The method according to claim 38, wherein in said step of adjusting (step (d)), said adjusted interpolated absorbance is obtained using the following equation:

Adjusted Interpolated Absorbance = (interpolated absorbance - y-intercept)/slope;

wherein, interpolated absorbance is as determined in said step of deriving (step (c)); and "y-intercept" and "slope" are obtained from said Second Linear Regression Equation, where said Second Linear Regression Equation is derived from a plot of electronically stored assigned absorbance measurements on an X-axis, and said interpolated absorbance measurements obtained on said recalibrated apparatus on a Y-axis, said Second linear regression equation having a y-intercept and a slope.

55. A method for Calibrating an apparatus comprising:

(i) obtaining absorbance measurements for at least one wavelength from a wavelength calibration table, of a Set of Calibrators on said apparatus, said apparatus lacking a primary calibration algorithm, and said set of calibrators having assigned absorbance values for at least one wavelength from a Standard Set of Wavelengths;

(ii) determining interpolated absorbance values for said absorbance measurements for at least one wavelength of a Standard Set of Wavelengths;

(iii) establishing a Second Linear Regression Equation in said apparatus for at least one wavelength of said Standard Set of Wavelengths, using said interpolated absorbance measurements and said assigned absorbance values; and

(iv) incorporating said Second Linear Regression Equation, and at least one Primary Calibration Algorithm on said apparatus, to produce a calibrated apparatus.

64. A medium storing instructions adapted to be executed by a processor to determine analyte concentration within a sample, as defined by the method of claim 56, said instructions comprising

i) said at least one calibration algorithm;

ii) assigned absorbances of said set of calibrators obtained from a first apparatus for at least one wavelength of a standard set of wavelengths; and

iii) identity of said first apparatus used to obtain said at least one primary calibration algorithm and said assigned absorbances.

65. A kit comprising said set of calibrators, said medium of claim 64 and instructions for use.

34. The method according to claim 33, wherein said set of calibrators, used on a First Apparatus and said Apparatus, are from the same batch.

37. The method according to claim 27, wherein in said step of determining (step ii), said Standard Set of Wavelengths comprise wavelengths from about 300nm to about 2500 nm.

38. The method according to claim 27, wherein, in said step of determining (step ii), said Standard Set of Wavelengths comprise wavelengths from about 500 nm to about 1100nm.

39. The method according to claim 27, where in said step of obtaining (step (i)), said absorbance measurements are determined one or more times at each wavelength of a wavelength calibration table, and either - an average of said first interpolated absorbance value is mapped to said Standard Set of Wavelengths, or - an average of said first absorbance measurements is interpolated and mapped to a standard set of wavelengths.

40. The method according to claim 27, wherein in said step of adjusting (step (d)), said adjusted interpolated absorbance is obtained using the following equation:

Adjusted Interpolated Absorbance = (interpolated absorbance - y-intercept)/slope;

wherein, interpolated absorbance is as determined in said step of measuring (step (c)); and "y-intercept" and "slope" are obtained from said first linear regression equation, where said First Linear Regression Equation is derived from a plot of interpolated absorbance measurements, said first interpolated absorbance measurements on a X-axis, and said second interpolated absorbance measurements on a Y-axis, said First linear regression equation having a y-intercept and a slope.

41. A method for Calibrating an apparatus comprising:

(i) obtaining absorbance measurements of a Set of Calibrators on said apparatus, said apparatus lacking a primary calibration algorithm and said set of calibrators having assigned absorbance values, (ii) determining interpolated absorbance values for said absorbance measurements for at least one wavelength of a Standard Set of Wavelengths,

(iii) establishing a Second Linear Regression Equation in said apparatus, using said interpolated absorbance measurements and said assigned absorbance values, and

(iv) incorporating said Second Linear Regression Equation, and at least one Primary Calibration Algorithm on said apparatus, to produce a calibrated apparatus.

68, 69 & 70. A medium storing instructions adapted to be executed by a processor to determine analyte concentration within a sample as defined by the method of claim 2, said instructions comprising

i) said at least one primary calibration algorithm,

ii) assigned absorbances of said set of calibrators obtained from said first apparatus; and

iii) identity of said first apparatus used to obtain said at least one primary calibration algorithm and said assigned absorbances.

71, 73 & 75. A kit comprising said set of calibrators, said medium of claim 68, and instructions for use.

<p>66. The kit of claim 65, wherein said set of calibrators are any type of calibrators suitable for producing one or more said second linear regression equations based on interpolated absorbances obtained using a first apparatus that is in control and interpolated absorbances obtained using a second apparatus.</p> <p>67. An apparatus for determining analyte concentration of a sample comprising a spectrophotometer, a light source, a power supply, a sample holder, a circuit board, a primary calibration algorithm, and said second linear regression equation, as defined in claim 56.</p> <p>76. A system for determining presence of an analyte comprising: i) means for transmitting electromagnetic radiation of one or more known wavelengths through a sample; ii) means for detecting electromagnetic radiation after transmission through said sample; iii) means for incorporating a primary calibration algorithm, iv) means for storing a wavelength calibration table and a standard set of wavelengths; v) means for deriving a first linear regression equation, a second linear regression equation, or both a first and a second linear regression equation; vi) means for detecting presence or concentration of an analyte within said sample.</p>	<p>72, 74 and 75. The kit of claim 71, wherein said set of calibrators are any type of calibrators suitable for producing one or more said first linear regression equations based on interpolated absorbances obtained using a first apparatus that is in control and interpolated absorbances obtained using a second apparatus.</p> <p>77. An apparatus for determining analyte concentration of a sample comprising a spectrophotometer, a light source, a power supply, a sample holder, a circuit board, a primary calibration algorithm, and said first linear regression equation as defined in claim 2.</p> <p>78. An apparatus for determining analyte concentration of a sample comprising a spectrophotometer, a light source, a power supply, a sample holder, a circuit board, a primary calibration algorithm, and said second linear regression equation as defined in claim 27.</p> <p>79. An apparatus for determining analyte concentration of a sample comprising a spectrophotometer, a light source, a power supply, a sample holder, a circuit board, a primary calibration algorithm, and said second linear regression equation, as defined in claim 42.</p> <p>80. A system for determining presence of an analyte comprising i) means for transmitting electromagnetic radiation of one or more known wavelengths through a sample, ii) means for detecting electromagnetic radiation after transmission through said sample, iii) means for incorporating a primary calibration algorithm, iv) means for storing a wavelength calibration table and a standard set of wavelengths, v) means for deriving a first linear regression equation, a second linear regression equation, or both a first and a second linear regression equation, vi) means for detecting presence or concentration of an analyte within said sample.</p>
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With respect to claims 42-67, the limitations of these claims have been noted in the rejection above. They are therefore considered rejected as set forth above.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the independent claims of the present application differ from the patented claims in having the phrase: "said similar set of calibrators", "for at least one wavelength of a standard set of wavelengths", "for at least one wavelength from a wavelength calibration table" or the equivalent language. In order to monitor the performance of an enterprise, applicant must base on a set of metric data points from

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software on one or more computer systems, performing three analytic tests based on the calibration table, a set of calibrators, and particularly to the model and analysis of the system resources. Therefore, the subject claims are broader than the Patent claims. It would therefore have been obvious to modify the claims of U.S. Patent No. 6,711,516 to claim the more limited "set of calibrators", "for at least one wavelength of a standard set of wavelengths", "for at least one wavelength from a wavelength calibration table".

3. Claims 21, 28, objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hien X. Vo whose telephone number is (571) 272-2282. The examiner can normally be reached on M-F (8:00-5:30) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on (571) 272-2269. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Hien Vo
Oct 29,04



MICHAEL NGHIEM
PRIMARY EXAMINER

11/10/04